



BOTULINUM TOXIN

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I. DESCRIPTION

Voluntary muscular contraction depends upon the release of acetylcholine from vesicles within a nerve ending following stimulation of the nerve. The acetylcholine is released into the neuromuscular junction, binding to specific proteins called receptors in the membrane of the muscle fiber. The effect of the acetylcholine at these receptors is to cause the muscle to contract. When a sufficient amount of acetylcholine has been released with subsequent binding to the muscle fiber proteins, muscle contraction occurs. Botulinum Toxin Type A and Botulinum Toxin Type B are neurotoxins produced by fermentation of the bacterium *Clostridium botulinum*. They interfere with neuromuscular transmission by creating a chemical blockade by inhibiting the release of acetylcholine from the nerve ending vesicles thereby preventing the acetylcholine from binding to the proteins in the receptor site on the muscle. Localized weakness or paralysis occurs in the muscle injected with Botulinum Toxin.

Each Botulinum neurotoxin product is unique and non-interchangeable. As a result of the heterogeneity inherent in complex biological products, the FDA does not allow data sets generated with any one biological product to be used in support of another product seeking regulatory approval.

Furthermore, although the units of many biological products are standardized, units of Botulinum neurotoxins are not. Thus, each Botulinum neurotoxin product requires unique doses. The FDA language clearly indicates this requirement in Botulinum neurotoxin products. Dosing of each product must be determined individually for each indication.

Caution should be exercised when administering Botulinum Toxin Type A and B to individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, motor neuropathy) or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert Eaton syndrome) Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise disorders where the patient has shown extreme sensitivity to the systemic effects of typical clinical doses.

II. POLICY/CRITERIA

1. Before consideration of coverage may be made in most cases it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other methods used to control and/or treat spastic condition. It is usually considered not medically necessary to give Botulinum Toxin injections for spastic conditions more frequently than every 90 days.

Botulinum Toxin A and Botulinum Toxin B may be a covered benefit for the following indications:

GI

- A. Anal fissures – chronic unresponsive to conservative treatments
- B. Esophageal achalasia

Neurology

- C. Blepharospasm
- D. Focal axillary hyperhidrosis
- E. Cerebral palsy
- F. Cervical dystonia
- G. Demyelinating diseases of the CNS and corpus callosum including Leukodystrophy
- H. Facial nerve VII disorders (facial myokymia, Melkersson's syndrome, facial/hemifacial spasms)
- I. Focal hand dystonia (i.e., organic writers cramp)
- J. Hereditary spastic paraplegia
- K. Lingual dystonia
- L. Multiple sclerosis
- M. Neuromyelitis optica
- N. Orofacial dyskinesia
- O. Schilder's disease
- P. Spastic Hemiplegia due to stroke or brain injury
- Q. Strabismus
- R. Torsion dystonia, idiopathic and symptomatic
- S. Torticollis
- T. Jaw-closing oromandibular dystonia

ENT

- U. Laryngeal spasm, laryngeal adductor spastic dysphonia or stridulus
- V. Ptyalism / sialorrhea (excessive secretion of saliva, drooling) that is refractory to pharmacotherapy
- W. Spasmodic dysphonia

OTHER

- X. Hyperhidrosis – see Hyperhidrosis Medical Policy #91451
- Y. Levator muscle spasm

Botulinum Toxin A is also covered benefit for **Headache**, including cervicogenic, cluster, migraine or tension headache if the following are met:



Disabling primary headaches and *one* of the following:

1. Failure to respond adequately to conventional treatments
2. Unacceptable side effects from conventional treatment
3. Standard preventive treatments are contraindicated
4. Coexistent jaw, head, or neck muscle spasm

2. The following indications are not covered:

- A. Use of Botulinum Toxin for the treatment of anal spasm, irritable colon, gastroparesis, biliary dyskinesia, craniofacial wrinkles or any treatment of other spastic conditions not listed as covered in this policy are considered to be experimental (including the treatment of smooth muscle spasm).
- B. Use of Botulinum Toxin for patients receiving aminoglycosides, which may interfere with neuromuscular transmission; or
- C. Use of Botulinum Toxin for patients with chronic paralytic strabismus, except to reduce antagonistic contractor in conjunction with surgical repair
- D. Treatment exceeding accepted dosage parameters unless supported by individual medical record review as well as treatments where the goal is to improve appearance rather than function.
- E. Use of Botulinum Toxin A or Botulinum Toxin B for all other conditions not listed above is not a covered benefit.

III. MEDICAL NECESSITY REVIEW

Required* Not Required Not Applicable

** Prior authorization is not required for Botulinum Toxin billed by neurologist or physiatrist.*

IV. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule, the Michigan Medicaid*



Provider Manual and the Michigan Medicaid Fee Schedule at:

http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html will govern.

- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. CODING INFORMATION

ICD9 codes:

These Diagnoses may support medical necessity

For ONLY Botulinum Toxin Type A (*Not covered for PriorityMedicare*)

- 307.81 Tension headache
- 339.00 Cluster headache syndrome, unspecified
- 339.01 Episodic cluster headache
- 339.02 Chronic cluster headache
- 339.03 Episodic paroxysmal hemicrania
- 339.04 Chronic paroxysmal hemicrania
- 339.05 Short lasting unilateral neuralgiform headache with conjunctival injection and tearing
- 339.09 Other trigeminal autonomic cephalgias
- 339.1 Tension type headache
- 339.10 Tension type headache, unspecified
- 339.11 Episodic tension type headache
- 339.12 Chronic tension type headache
- 339.4 Complicated headache syndromes

- 346.00 Migraine with aura, without mention of intractable migraine without mention of status migrainosus
- 346.01 Migraine with aura, with intractable migraine, so stated, without mention of status migrainosus
- 346.02 Migraine with aura, without mention of intractable migraine with status migrainosus
- 346.03 Migraine with aura, with intractable migraine, so stated, with status migrainosus
- 346.10 Migraine without aura, without mention of intractable migraine without mention of status migrainosus
- 346.11 Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
- 346.12 Migraine without aura, without mention of intractable migraine with status migrainosus
- 346.13 Migraine without aura, with intractable migraine, so stated, with status migrainosus
- 346.20 Variants of migraine, not elsewhere classified, without mention of intractable migraine without mention of status migrainosus
- 346.21 Variants of migraine, not elsewhere classified, with intractable migraine, so stated, without mention of status migrainosus
- 346.22 Variants of migraine, not elsewhere classified, without mention of intractable migraine with status migrainosus
- 346.23 Variants of migraine, not elsewhere classified, with intractable migraine, so stated, with status migrainosus
- 346.3 Hemiplegic migraine



- 346.30 Hemiplegic migraine, without mention of intractable migraine without mention of status migrainosus
- 346.31 Hemiplegic migraine, with intractable migraine, so stated, without mention of status migrainosus
- 346.32 Hemiplegic migraine, without mention of intractable migraine with status migrainosus
- 346.33 Hemiplegic migraine, with intractable migraine, so stated, with status migrainosus
- 346.40 Menstrual migraine, without mention of intractable migraine without mention of status migrainosus
- 346.41 Menstrual migraine, with intractable migraine, so stated, without mention of status migrainosus
- 346.42 Menstrual migraine, without mention of intractable migraine with status migrainosus
- 346.43 Menstrual migraine, with intractable migraine, so stated, with status migrainosus
- 346.50 Persistent migraine aura without cerebral infarction, without mention of intractable migraine without mention of status migrainosus
- 346.51 Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
- 346.52 Persistent migraine aura without cerebral infarction, without mention of intractable migraine with status migrainosus
- 346.53 Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, with status migrainosus
- 346.60 Persistent migraine aura with cerebral infarction, without mention of intractable migraine without mention of status migrainosus
- 346.61 Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus
- 346.62 Persistent migraine aura with cerebral infarction, without mention of intractable migraine with status migrainosus
- 346.63 Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, with status migrainosus
- 346.70 Chronic migraine without aura, without mention of intractable migraine without mention of status migrainosus
- 346.71 Chronic migraine without aura, with intractable migraine, so stated, without mention of status migrainosus
- 346.72 Chronic migraine without aura, without mention of intractable migraine with status migrainosus
- 346.73 Chronic migraine without aura, with intractable migraine, so stated, with status migrainosus
- 346.80 Other forms of migraine, without mention of intractable migraine without mention of status migrainosus
- 346.81 Other forms of migraine, with intractable migraine, so stated, without mention of status migrainosus
- 346.82 Other forms of migraine, without mention of intractable migraine with status migrainosus
- 346.83 Other forms of migraine, with intractable migraine, so stated, with status migrainosus
- 346.90 Migraine, unspecified without mention of intractable migraine without mention of status migrainosus
- 346.91 Migraine, unspecified with intractable migraine, so stated, without mention of status migrainosus



- 346.92 Migraine, unspecified, without mention of intractable migraine with status migrainosus
- 346.93 Migraine, unspecified, with intractable migraine, so stated, with status migrainosus

- 728.85 Spasm of muscle

For Botulinum Toxins Type A and B:

- 330.0 Leukodystrophy
- 333.2 Myoclonus
- 333.3 Tics of organic origin
- 333.6 Idiopathic torsion dystonia
- 333.71 Acquired torsion dystonia
- 333.72 Acute dystonia
- 333.79 Symptomatic torsion dystonia
- 333.81 Blepharospasm
- 333.82 Orofacial dyskinesia
- 333.83 Spasmodic torticollis
- 333.84 Organic writers' cramp
- 333.89 Other fragments of torsion dystonia
- 334.1 Hereditary spastic paraplegia
- 340 Multiple sclerosis
- 341.0 Neuromyelitis optica
- 341.1 Schilder's disease
- 341.8 Other demyelinating diseases of central nervous system
- 341.9 Unspecified demyelinating disease of central nervous system
- 342.10 Spastic hemiplegia affecting unspecified side
- 342.11 Spastic hemiplegia affecting dominant side
- 342.12 Spastic hemiplegia affecting nondominant side
- 343.0 Diplegic infantile cerebral palsy
- 343.1 Hemiplegic infantile cerebral palsy
- 343.2 Quadriplegic infantile cerebral palsy
- 343.3 Monoplegic infantile cerebral palsy
- 343.4 Infantile hemiplegia
- 343.8 Other specified infantile cerebral palsy
- 343.9 Unspecified infantile cerebral palsy
- 344.00 Unspecified quadriplegia
- 344.01 Quadriplegia and quadriparesis, C1-C4, complete
- 344.02 Quadriplegia and quadriparesis, C1-C4, incomplete
- 344.03 Quadriplegia and quadriparesis, C5-C7, complete
- 344.04 C5-C7, incomplete
- 344.09 Other quadriplegia and quadriparesis
- 344.1 Paraplegia
- 344.2 Diplegia of upper limbs
- 344.30 Monoplegia of lower limb affecting unspecified side
- 344.31 Monoplegia of lower limb affecting dominant side
- 344.32 Monoplegia of lower limb affecting nondominant side
- 344.40 Monoplegia of upper limb affecting unspecified side
- 344.41 Monoplegia of upper limb affecting dominant side
- 344.42 Monoplegia of upper limb affecting nondominant side
- 344.5 Unspecified monoplegia
- 351.8 Other facial nerve disorders



- 374.13 Spastic ectropion
- 378.00 Unspecified esotropia
- 378.01 Monocular esotropia
- 378.02 Monocular esotropia with A pattern
- 378.03 Monocular esotropia with V pattern
- 378.04 Monocular esotropia with other noncomitancies
- 378.05 Alternating esotropia
- 378.06 Alternating esotropia with A pattern
- 378.07 Alternating esotropia with V pattern
- 378.08 Alternating esotropia with other noncomitancies
- 378.10 Unspecified exotropia
- 378.11 Monocular exotropia
- 378.12 Monocular exotropia with A pattern
- 378.13 Monocular exotropia with V pattern
- 378.14 Monocular exotropia with other noncomitancies
- 378.15 Alternating exotropia
- 378.16 Alternating exotropia with A pattern
- 378.17 Alternating exotropia with V pattern
- 378.18 Alternating exotropia with other noncomitancies
- 378.20 Unspecified intermittent heterotropia
- 378.21 Intermittent esotropia, monocular
- 378.22 Intermittent esotropia, alternating
- 378.23 Intermittent exotropia, monocular
- 378.24 Intermittent exotropia, alternating
- 378.30 Unspecified heterotropia
- 378.31 Hypertropia
- 378.32 Hypotropia
- 378.33 Cyclotropia
- 378.34 Monofixation syndrome
- 378.35 Accommodative component in esotropia
- 378.40 Unspecified heterophoria
- 378.41 Esophoria
- 378.42 Exophoria
- 378.43 Vertical heterophoria
- 378.44 Cyclophoria
- 378.45 Alternating hyperphoria
- 378.50 Unspecified paralytic strabismus
- 378.51 Paralytic strabismus, third or oculomotor nerve palsy, partial
- 378.52 Paralytic strabismus, third or oculomotor nerve palsy, total
- 378.53 Paralytic strabismus, fourth or trochlear nerve palsy
- 378.54 Paralytic strabismus, sixth or abducens nerve palsy
- 378.55 Paralytic strabismus, external ophthalmoplegia
- 378.56 Paralytic strabismus, total ophthalmoplegia
- 378.60 Unspecified mechanical strabismus
- 378.61 Mechanical strabismus from Brown's (tendon) sheath syndrome
- 378.62 Mechanical strabismus from other musculofascial disorders
- 378.63 Mechanical strabismus from limited duction associated with other conditions
- 378.71 Duane's syndrome
- 378.72 Progressive external ophthalmoplegia
- 378.73 Strabismus in other neuromuscular disorders
- 378.81 Palsy of conjugate gaze



- 378.82 Spasm of conjugate gaze
- 378.83 Convergence insufficiency or palsy in binocular eye movement
- 378.84 Convergence excess or spasm in binocular eye movement
- 378.85 Anomalies of divergence in binocular eye movement
- 378.86 Internuclear ophthalmoplegia
- 378.87 Other dissociated deviation of eye movements
- 378.9 Unspecified disorder of eye movements
- 438.20 Hemiplegia affecting unspecified side
- 438.21 Hemiplegia affecting dominant side
- 438.22 Hemiplegia affecting nondominant side
- 438.30 Monoplegia of upper limb affecting unspecified side
- 438.31 Monoplegia of upper limb affecting dominant side due to cerebrovascular disease
- 438.32 Monoplegia of upper limb affecting nondominant side due to cerebrovascular disease
- 438.41 Monoplegia of lower limb affecting dominant side due to cerebrovascular disease
- 438.42 Monoplegia of lower limb affecting nondominant side due to cerebrovascular disease
- 438.50 Other paralytic syndrome affecting unspecified side
- 438.51 Other paralytic syndrome affecting dominant side
- 438.52 Other paralytic syndrome affecting nondominant side
- 438.53 Other paralytic syndrome, bilateral
- 478.33 Bilateral partial paralysis of vocal cords or larynx
- 478.34 Bilateral complete paralysis of vocal cords or larynx
- 478.75 Laryngeal spasm
- 527.7 Disturbance of salivary secretion
- 530.0 Achalasia and cardiospasm
- 565.0 Anal fissure (*Not covered for Priority Medicare*)
- 705.21 Primary focal hyperhidrosis
- 780.8 Generalized hyperhidrosis
- 723.5 Torticollis, unspecified
- 729.89 Other musculoskeletal symptoms referable to limbs
- 754.1 Congenital musculoskeletal deformity of sternocleidomastoid muscle
- 781.0 Abnormal involuntary movements
- 784.40 Unspecified voice disturbance
- 784.49 Other voice disturbance
- 784.5 Other speech disturbance
- 907.0 Late effect of intracranial injury without mention of skull fracture
- 907.1 Late effect of injury to cranial nerve

CPT/HCPCS Procedure Codes:

- J0585 Botulinum toxin type A, per unit
- J0586 Injection, abobotulinum toxin A, 5 units
- J0587 Botulinum toxin type B, per 100 units

- 31513 Laryngoscopy, indirect; with vocal cord injection
- 31570 Laryngoscopy, direct, with injection into vocal cord(s), therapeutic;
- 31571 Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope
- 43201 Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance



- 43236 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance
- 46505 Chemodenervation of internal anal sphincter
- 64612 Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (eg, for blepharospasm, hemifacial spasm)
- 64613 Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)
- 64614 Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)
- 64650 Chemodenervation of eccrine glands; both axillae
- 64653 Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
- 67345 Chemodenervation of extraocular muscle

VI. REFERENCES

- Botulinum Toxin, Blue Cross Blue Shield of Massachusetts, Policy:006, January 2002.
- Botulinum Toxin Type A Injection, The Regence Group, Policy No. 6, February 8, 2002.
- Botulinum Toxins, Medicare Coverage Policy, L19769, CMS Region 5, effective date January 1, 2006
- Botulinum Toxin, Aetna Coverage Policy Bulletin, Number 0113, February 1, 2002
- Botulinum Toxin Type A, Humana, 2002
- Botulinum Toxin Treatment for Hyperhidrosis, HAYES, Inc.,
Published: September 20, 2005
- Botulinum Toxin Treatment for Dystonias, HAYES, Inc., Published: February 12, 2006
- Botulinum Toxin for Spasticity and Gastrointestinal Disorders, HAYES, Inc.,
December 8, 2003.
- Botulinum Toxin Treatment for Headache, HAYES, Inc., November 4, 2003
- Botulinum Toxin Treatment for Movement Disorders, HAYES, Inc. March 2002
- Blumenfeld, A.M., et al. "Procedures for administering Botulinum Toxin Type A for migraine and tension-type headache", Headache, 2003; 43:884-891.

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